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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,751	11/01/2001	Alan T. Remaley	15280-3931US	7562

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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,751	REMALEY ET AL.	
	Examiner	Art Unit	
	David J Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/8/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *22-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants' election of Group I, claims 1-21, with traverse in the reply filed on November 8, 2004, is acknowledged. Applicants argue that the inventions of Group I and Group II do not satisfy the definitions of "independent" and "distinct" as set forth in 35 USC 121 and MPEP 802.01. Applicants also argue that no additional burden would be imposed for a simultaneous examination of Groups I and II. However, the current application appears to be a national stage application of international application PCT/US00/14827. As such, the "independent" and "distinct" requirements and "search burden" requirement normally associated with restriction practice in US patent application cases are not applicable here. As stated in the previous Office Action, the technical feature linking Group I with Group II does not constitute a special technical feature as defined by PCT Rule 13.2 because the technical feature does not define a contribution over the prior art. Van Veldhoven et al., 258 ANAL. BIOCHEM. 152 (1998), also teaches a kit for determining amounts of cholesterol in a sample comprising a complex-forming agent (see p. 153, col. 1, "(tauro)cholate", "bile acids") and a non-denaturing detergent (see p. 153, col. 1, "deoxycholate", "Triton X-100"). Therefore, unity of invention is lacking because the technical feature linking the inventions of Groups I and II does not constitute a special technical feature as defined by PCT Rule 13.2, as the technical feature does not define a contribution over the prior art. The restriction requirement is deemed proper and is made FINAL.

Claims 22-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim.

Applicants' election of Group I antibody species (i.e. Invention I(A1)) is acknowledged. Claim 7 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Accordingly, claims 1-6 and 8-21 are before the Examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 8-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 4-6, 17 and 19, the recitation of "fraction" is indefinite because it is not clear whether/how a sample is fractioned or fractionated, or what mathematical operations are required for the determination of "fraction" or what physical parameters consist or comprise "fraction." In claim 1, the recitations of "fraction in the sample" or "fraction present in the sample" are indefinite because it is not clear whether/how said fractions are created, identified, isolated, separable, distinguishable, or is physically divided from the rest of the sample. In claim 1, the recitation of "a second lipoprotein fraction" is indefinite because it is not clear whether/how said second fraction is created, identified, isolated, separable, distinguishable, or is physically divided from the first lipoprotein fraction or from the rest of the sample. In addition, in claims 17 and 19, the recitation of "fraction consists of... in the sample" is indefinite because it is not clear how a fraction *consisting of* a particular lipoprotein can be created, identified,

isolated, separable, distinguishable, or is physically divided from a sample (e.g. serum, plasma) when the sample comprises lipoproteins and many other components.

In claim 1, step (b) the recitation of "a first cholesterol value" is indefinite because it is not clear how this value is used in the overall determination of cholesterol. The overall method of determining cholesterol does not appear to require "a first cholesterol value" after "a first cholesterol value" is obtained in step (b). Therefore, its purpose is unclear.

In claim 1, step (d), the recitation of "thus determining the amount of cholesterol in the first and second lipoprotein fractions..." (emphasis added) is indefinite because it is not clear how "determining the amount of cholesterol in the first and second lipoprotein fractions" results from "measuring the total amount of cholesterol present in the sample." In addition, it is not clear what steps are required for "determining the amount of cholesterol in the first and second lipoprotein fractions..." or whether "determining the amount of cholesterol in the first and second lipoprotein fractions..." requires the step of measuring the amount of cholesterol in the first and second lipoprotein fractions or why it is necessary to repeat the measurement of the amount of cholesterol in the second lipoprotein fraction, which was already performed in prior step (b).

In claim 1, recitation of conditional language "with the proviso that" does not create a positive or negative claim limitation and is therefore considered indefinite.

In claims 2 and 3, recitation of conditional language "provided that" does not create a positive or negative claim limitation and is therefore considered indefinite.

In claim 8, the recitation of "said first lipoprotein" lacks antecedent basis.

In claims 10-11, the recitation of "the measuring of the amount of cholesterol present in steps (b) and (d) is performed by reacting... with cholesterol esterase" renders claim 1 indefinite. It is not clear how it is possible to measure the total amount of cholesterol in step (d) when an amount of cholesterol was already consumed by reaction with cholesterol esterase in step (b). Similarly, in claim 11, the recitation of "said cholesterol is reacted with cholesterol oxidase or cholesterol dehydrogenase" renders claim 1 indefinite because it is not clear how it is possible to measure the total amount of cholesterol in step (d) when an amount of cholesterol was already consumed by reaction with cholesterol oxidase or cholesterol dehydrogenase in step (b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 8-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Miki et al. (US 6,162,607).

Miki et al. teach a method for determining amounts of cholesterol (see Abstract, "specifically for measuring the amount of cholesterol") in lipoprotein fractions (see col. 2, lines 62+, "any one of these lipoproteins can be selected as the specific lipoprotein to be the object of the measurement") in a sample (see Abstract, "serum and plasma") comprising the steps of: contacting a first lipoprotein fraction in the sample (see col. 6, line 15, "biological sample such as serum and/or plasma") with a complex-forming agent (see col. 6, line 16, "a first solution comprising an antibody reactive to lipoproteins(s)") to form a complex of said first lipoprotein fraction with the complex-forming agent (see col. 4, lines 1-4, "agglutination caused by the reaction of the antibody with lipoprotein(s)") with the proviso that the complex is not a substrate for cholesterol esterase (see col. 3, lines 21-28, "The antibody... may include any one such as having an effect of preventing the objective constituents for measurement... from participating in the reaction with a reagent for measuring the amount of the objective constituents"), measuring the amount of cholesterol associated with a second lipoprotein fraction to obtain a first cholesterol value (see col. 2, lines 16-17, "measuring the absorbance (OD_1) of the reaction mixture"), dissociating the first lipoprotein fraction from the complex-forming agent (see col. 5, line 29-31, "The reagent solution containing no antibody (the 2nd solution)... further comprises a surfactant", (noting that the surfactant of Miki et al. necessarily causes dissociation of the first lipoprotein fraction from the complex forming agent, and would be so recognized by persons of ordinary skill in the art. *See e.g.* col. 5, lines 64-57, "when the surfactant is added to the first solution, measurement error caused by the objective constituent contained in lipoproteins other than the specific lipoprotein may be observed")), and measuring the total amount of cholesterol present in the sample (see col. 2, lines 20-21, "measuring again the absorbance (OD_2) of the latter reaction mixture").

With respect to claims 2-3, Miki et al. teach a method for determining amounts of cholesterol wherein the complex is not a substrate for cholesterol oxidase or cholesterol dehydrogenase (see col. 3, lines 21-28, "The antibody... may include any one such as having an effect of preventing the objective constituents from measurement... from participating in the reaction with a reagent for measuring the amount of the objective constituents").

With respect to claim 4, Miki et al. teach a method for determining amounts of cholesterol wherein said first lipoprotein fraction is HDL-C (see col. 3, line 39, "anti-apolipoprotein A").

With respect to claim 5, Miki et al. teach a method for determining amounts of cholesterol wherein said first lipoprotein fraction is LDL-C (see col. 3, line 39, "anti-apolipoprotein B").

With respect to claim 6, Miki et al. teach a method for determining amounts of cholesterol wherein said complex-forming agent is an anti-lipoprotein antibody (see col. 3, lines 21-42).

With respect to claims 8-9, Miki et al. teach a method for determining amounts of cholesterol wherein a non-denaturing detergent deoxycholate is used (see col. 5, line 49, "deoxy cholic acid").

With respect to claims 10-11, Miki et al. teach a method for determining amounts of cholesterol wherein the measuring of the amount of cholesterol is performed by reaction with cholesterol esterase, cholesterol oxidase, or cholesterol dehydrogenase (see col. 4, line 63 to col. 5, line 4).

With respect to claim 12, Miki et al. teach a method for determining amounts of cholesterol wherein the first cholesterol value is subtracted from the total amount of cholesterol (see col. 2, line 25, "difference between OD_1 and OD_2").

With respect to claims 13-15, Miki et al. teach a method for determining amounts of cholesterol wherein an optical means is used to detect a dye indicator molecule (see col. 5, line 4, "nicotinamide adenine dinucleotide (NAD)").

With respect to claim 16, Miki et al. teach a method for determining amounts of cholesterol further comprising the step of determining the amount of any triglycerides (see col. 3, line 19).

With respect to claims 17-20, Miki et al. teach a method for determining amounts of cholesterol wherein the first lipoprotein fraction consists of apoB-containing lipoprotein or HDL-C (see col. 3, line 39, "anti-apolipoprotein A, anti-apolipoprotein B").

With respect to claim 21, Miki et al. teach a method for determining amounts of cholesterol wherein said antibody specifically binds to apoAI or apoAII (see col. 3, line 39, "anti-apolipoprotein A"). A person of ordinary skill in the art would recognize that the anti-apolipoprotein A antibody of Miki et al. would encompass either apoAI or apoAII.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
Art Unit 1641

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11/29/04